

What is claimed is:

1. A prosthetic heart valve assembly comprising in combination:

(a) an annular structure comprised of a moldable, physiologically acceptable, non-

5 biodegradable, implantable plastic and having a longitudinal cylindrical passageway defining a sidewall portion that has a pair of bearing block receiving windows defined therein, each said window being generally diametrically opposed relative to the other;

10 (b) a pair of bearing blocks, each said bearing block being comprised of pyrolytic carbon and being seated in a different one of said windows, and each said bearing block having a substantially flat interior face, a pair of circumferentially spaced bearing recesses defined in said interior face, and perimeter edge portions interlockingly and sealingly engaged with said so seated window; and

15 (c) a pair of leaflets, each said leaflet being comprised of pyrolytic carbon and being adjacent to the other thereof and transversely disposed across said passageway, each said leaflet having a generally flat body portion whose perimeter includes a generally arcuately extending outside edge region, a straight inside edge region, and a pair of straight, spaced, parallel, side edge regions that each extend between and join a different adjacent terminal portion of each of said outside and said inside edge regions, and each one of said side edge regions having a medially located, integral, outwardly extending, flattened, peripherally rounded, ear-like projection;

20 the interrelationship between said leaflets, said ear-like projections and said bearing blocks and said bearing recesses being such that each of said ear like projections is receivable in and pivotably associated with a different one of said bearing recesses in each of said bearing blocks whereby said leaflets can pivot between valve open and valve closed positions; and

25 said annular structure is unitarily molded *in situ* about said perimeter edge portions.

2. The prosthetic heart valve assembly of claim 1 wherein said annular structure has a

generally cylindrical sidewall portion that defines said longitudinal passageway and that has respective opposite end portions that extend circumferentially in longitudinally spaced, parallel relationship.

3. The prosthetic heart valve assembly of claim 2 wherein said respective opposite end portions each have an outwardly and circumferentially extending rim flange portion.

4. The prosthetic heart valve assembly of claim 1 wherein said bearing blocks and said leaflets are initially held in a connected relationship wherein said interior face of each said bearing block is in spaced, parallel relationship relative to the other thereof, and each said ear-like projection is pivotably associated with a different bearing recess.

5 5. The prosthetic heart valve assembly of claim 1 wherein

(a) each said leaflet is responsive to fluid pressure applied against an upstream side of said passageway, and

10 (b) said leaflets cooperate so that, responsive to changes in said applied fluid pressure, each pivots between a first position where said passageway is substantially fully closed to a second position where said passageway is substantially fully open, thereby defining respective valve closed and valve open configurations relative to said passageway.

6. A prosthetic heart valve assembly comprising in combination:

15 (a) an annular structure comprised of a moldable, physiologically acceptable, non-biodegradable, implantable plastic and having sidewall portions that define a generally cylindrical, longitudinal passageway therethrough, opposite end portions that extend circumferentially in longitudinally spaced, parallel relationship, and circumferentially extending rim flange portions defined about each said opposite end portion, and having a pair of bearing block receiving windows defined in said sidewall portions, each said window being generally diametrically opposed relative to the other;

20 (b) a pair of bearing blocks, each said bearing block being comprised of pyrolytic carbon and being seated in a different one of said windows, and each said bearing block having a substantially flat interior face, a pair of circumferentially spaced bearing recesses defined in said interior face, and perimeter edge portions interlockingly and sealingly engaged with said respective seated window; and

25 (c) a pair of leaflets, each said leaflet being comprised of pyrolytic carbon and being adjacent to the other thereof and transversely disposed across said passageway, each said leaflet having a generally flat body portion whose perimeter includes a generally arcuately extending outside edge region, a straight inside edge region, and a pair of straight, spaced, parallel, side edge regions that each extend between and join a different adjacent terminal portion of each of said

outside and said inside edge regions, and each one of said side edge regions having a medially located, integral, outwardly extending, flattened, peripherally rounded, ear-like projection, said ear-like projections of each said leaflet being pivotably engagable with a different one bearing recess of each one of said bearing blocks;

5 the interrelationship between said leaflets, said ear-like projections and said bearing blocks and said bearing recesses being such that each of said ear like projections is receivable in and pivotably associated with a different one of said bearing recesses in each of said bearing blocks whereby said leaflets can pivot between valve open and valve closed positions; and

said annular structure is unitarily molded *in situ* about said perimeter edge portions.

10 7. The prosthetic heart valve assembly of claim 6 wherein said bearing blocks and said leaflets, during said *in situ* molding of said annular structure, are initially held in a connected relationship with said interior face of each said bearing block is in spaced, parallel relationship relative to the other thereof, and with each said ear-like projection being pivotably associated with a different bearing recess in each said bearing block.

15 8. The prosthetic heart valve assembly of claim 6 wherein

(a) each said leaflet is responsive to fluid pressure applied against an upstream side of said passageway, and

20 (b) said leaflets cooperate so that, responsive to changes in said applied fluid pressure, each pivots between a first position where said passageway is substantially fully closed to a second position where said passageway is substantially fully open, thereby defining respective valve closed and valve open configurations relative to said passageway.

9. A method for fabricating a prosthetic heart valve assembly of claim 1 comprising the steps of:

25 (a) associating each of said leaflets with each of said bearing blocks with the respective ear like projection of each said leaflet associated with a different said bearing recess of each said bearing block so that each said leaflet is pivotable relative to each said bearing block;

(b) associating each of said bearing blocks as so associated with said leaflets with a mold for molding said annular structure so that each said bearing block is located in a different one of said opposed windows of said annular structure as molded in said mold and so that said mold and

said bearing blocks in combination define a molding cavity that defines said annular structure; and

- (c) molding said annular structure in said molding cavity with said plastic.